JUL 22 2009

510(k) Summary

Percutaneous Systems, Inc.'s Coaxial Accordion ERCP Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Percutaneous Systems, Inc.
3260 Hillview Avenue Suite 100
Palo Alto, CA 94304

Phone: (650) 493 - 4200
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Contact Person: Thomas Lawson

Date Prepared: February 20, 2009

Common or Usual Name

Biliary Catheter

Classification Name

Biliary Catheter and Accessories

Predicate Devices

Coaxial Accordion Stone Management Device, Percutaneous Systems, Inc.
Fusion Extraction Balloon with Multiple Sizing, Cook Medical

Intended Use

The Coaxial Accordion ERCP Device is intended to be used for endoscopic removal of stones in the biliary system and for contrast injection.

Technological Characteristics

The Coaxial Accordion ERCP Device consists of a film membrane attached onto a catheter.

Performance Data

Not required.

Substantial Equivalence

The Coaxial Accordion ERCP Device has the same intended use, indications for use, and principles of and very similar technological characteristics as the predicate devices. Thus, the Coaxial Accordion ERCP Device is substantially equivalent to the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2009

Thomas Lawson, Ph.D.
VP, Clinical & Regulatory Affairs
Percutaneous Systems, Inc.
3260 Hillview Avenue
Suite 100
PALO ALTO CA 94304

Re: K090485
Trade/Device Name: Coaxial Accordion ERCP Device
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Codes: LQR, GCA and FGE
Dated: July 13, 2009
Received: July 15, 2009

Dear Dr. Lawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090485

Device Name: Coaxial Accordion ERCP Device

Indications for Use:

The Coaxial Accordion ERCP Device is intended to be used for endoscopic removal of stones in the biliary system and for contrast injection.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090485